

U.S. Serial No. 09/888,920

Amendment to Office Action dated June 29, 2005

Remarks

Claims 27 and 41 have been amended, and new claims 47 and 48 have been added. Claims 30-34 and 40 remain withdrawn. Support for the amendments and new claim can be found in the specification, claims, and drawings as originally filed. No new matter has been added.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 27-29, 35-39, and 41-46 are rejected as failing to comply with the written description requirement. Applicants respectfully traverse the rejection. Independent claim 27 recites a hub having a lumen with a substantially fixed diameter along its length, and independent claim 41 recites a hub with a lumen having a substantially fixed diameter extending through a connector and strain relief. This feature is described in the specification and is shown in the drawings as originally filed. The specification describes one embodiment in which the hub assembly is integrally molded in one piece by insert molding. The specification describes the process in which a mandrel is inserted into the end of a catheter tube, which is placed in a mold, and molten material is injected into the mold to form the hub assembly. One of ordinary skill in the art would understand this process to result in a hub with a lumen formed by the mandrel and catheter tube, which provide a lumen having a substantially fixed diameter extending through the hub.

Additionally, the feature of a substantially fixed lumen is shown in FIG. 2, where the lumen 40 extending through the hub 16 is in fluid communication with catheter lumen 14. Applicants submit that the lumen 40 is shown in FIG. 2 as substantially fixed. With respect to FIG. 3, the specification states that "[o]ther than the strain relief 106, hub assembly 100 can in all respects be similar to hub assembly 10", which is shown in FIG. 2. Thus, the lumen through hub assembly 100 in FIG. 3 is similar to that shown in FIG. 2, which shows a substantially fixed lumen extending through the hub.

The feature of a lumen having a uniform diameter through the strain relief and at least a portion of the connector, recited in independent claim 41, is similarly shown in FIGS. 2 and 3. Applicants submit that the instant specification and drawings do provide a description of the features of independent claims 27 and 41, as amended, and also

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describe the embodiment of new claim 47. Withdrawal of the rejection is respectfully requested.

Drawing Objection

The drawings are objected to for not showing every feature of the invention specified in the claims. Applicants submit that the drawings as filed show every feature of the invention as claimed, for at least the reasons set forth above. In particular, the combination of FIGS. 2 and 3 provide an illustration of the features recited in the claims. Withdrawal of the drawing objection is respectfully requested.

Rejection under 35 U.S.C. § 103 (a)

Claims 27-29, 35-39, and 41-46 are rejected as being unpatentable over Wijkamp et al. (US 5,167,647) in view of Long et al. (US 4,632,488). Applicants respectfully traverse the rejection. Independent claim 27, as amended, recites an integral catheter tube hub having a proximal portion configured as a connector, a distal portion configured as a strain relief, and a continuous lumen wall extending through the hub, where the proximal and distal portions of the hub are formed of only one or two layers of material surrounding the lumen. Neither Wijkamp et al., Long et al., nor a combination of the two references teaches such a device. Wijkamp et al. teach a catheter hub and strain relief in which either a separate hub 6, strain relief tube 5, and tubular body 2 are glued together, or the hub 13 is placed in a mold with tubular catheter body 12 and the strain relief is formed around the hub 13 and catheter body 12. Wijkamp et al. thus teach forming a hub assembly having three layers. See column 2, lines 51-54 and column 3, lines 6-9, 35-41, 48-52, and 58-60. The three layer construction of the hub of Wijkamp et al. is shown in FIG. 1, with tubular body 2 extending the entire length of the strain relief 5, such that the coupling element 6 has three layers surrounding the lumen.

Long et al. teach a cord strain relief and clamping device in which the lumen is adjustable in diameter in the clamping component 26, and in which the cord to be retained passes through the entire device, rather than having an end being retained in the hub. Applicants submit that there is no motivation for one of ordinary skill in the art to combine the teachings of Wijkamp et al. and Long et al. The Examiner asserts that one

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would have been motivated to make the combination to provide a resilient snug fit having greater resistance to the catheter bending sharply adjacent to the hub. However, the Examiner has provided no reasoning or teaching to support the assertion. There is no indication in Wijkamp et al. that the tubular strain relief 5 does not provide a resilient snug fit or resistance to the catheter bending sharply adjacent to the hub. Additionally, Long et al. teach a strain relief, but does not provide any indication that it achieves a greater resistance to the catheter bending sharply adjacent to a hub.

To the contrary, Applicants submit that one of ordinary skill in the art would believe the strain relief of Long et al. to have less resistance to a catheter bending sharply adjacent to the hub because of the spaces between the turns. One would expect such a structure to bend easier than the solid tubular strain relief specifically taught by Wijkamp et al. It appears the motivation for combining Wijkamp et al. and Long et al. actually comes from either Applicants' own specification, which is improper, or the level of skill in the art, which is also improper. MPEP 2143.01 states "[t]he level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999)."

Furthermore, Applicants submit that even if one were to combine the teachings of Wijkamp et al. and Long et al., one would not arrive at the claimed invention. At best, a combination would appear to result in the device of Wijkamp et al. with the strain relief and clamping member of Long et al. substituted for the tubular strain relief 5 of Wijkamp et al. Such a combination would appear to have three layers of material surrounding the lumen, i.e. the tubular body 2 and coupling element 6 of Wijkamp et al. and the cord clamping component/bushing component/strain relief of Long et al. The combination thus does not teach or suggest each and every element of claim 27, as amended.

Independent claim 41, as amended, recites a unitary catheter tube hub having a connector, a strain relief, and a lumen with a substantially fixed diameter, where a single layer of material forms the lumen wall in the connector and strain relief. As stated above, the device of Wijkamp et al. appears to have three layers surrounding the lumen in the connector and strain relief. Long et al. teach a device with a cord clamping component/bushing component/strain relief element (26, 24, 22) disposed within a housing 90, to form a lumen wall with at least two layers of material. Any combination

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of Wijkamp et al. and Long et al. thus fail to teach or suggest the elements of independent claim 41, as amended.

Wijkamp et al. and Long et al., either alone or in combination thus fail to teach or suggest each and every element of the independent claims, and the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

Claims 29, 35, 44, and 45 appear to be rejected as being unpatentable over Davila (US 5,466,230) in view of Klump, Jr. (US 2,724,736) and Lalikos. However, the rejection is incomplete and does not include the primary references used to reject the independent claims. Applicants respectfully request clarification of any further rejections of these claims. Neither Davila nor Klump, Jr. appear to teach or suggest the elements of the independent claims, as amended, or the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

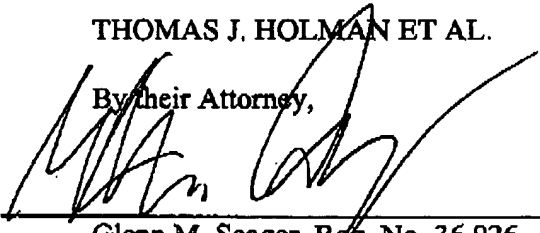
Reexamination and reconsideration are respectfully requested. Any inquiry regarding this matter may be directed to the undersigned representative at (612) 677-9050.

Respectfully submitted,

THOMAS J. HOLMAN ET AL.

By their Attorney,

Date: Sept. 23, 2005


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